

INTERNATIONAL  
STANDARD

**ISO**  
**5366-1**

Third edition  
1994-02-01

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**Tracheostomy tubes —**

**Part 1:**

Connectors for tubes for adults

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*Tubes de trachéostomie —*

*Partie 1: Raccords pour tubes pour adultes*

ISO 5366-1:1994

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Reference number  
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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5366-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 2, *Tracheal tubes and other equipment*.

This third edition cancels and replaces the second edition (ISO 5366-1:1986), of which it constitutes a technical revision.

ISO 5366 consists of the following parts, under the general title *Tracheostomy tubes*:

- Part 1: *Connectors for tubes for adults*
- Part 2: *Basic requirements for tubes for adults*
- Part 3: *Paediatric tracheostomy tubes*

Annex A of this part of ISO 5366 is for information only.

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## Introduction

There are many advantages in harmonizing the requirements for connectors for tracheostomy tubes with those already widely used for tracheal tubes.

The patient connection port of the breathing system of an anaesthetic machine or ventilator is a coaxial 22 mm male/15 mm female conical connector, an important purpose of the smaller connector being to mate with the 15 mm male tracheal tube connector. It is, therefore, advantageous to use the same size of fitting for tracheostomy tubes used for patients during surgical operations and for those for whom artificial ventilation or other respiratory support may be required.

Inadvertent disconnection of the breathing system from the tracheostomy tube is a well-recognized hazard and it is therefore specified for adult tubes (tubes of designated inside diameter of 6,5 mm or greater) that the male 15 mm conical fitting shall be permanently attached to the tracheostomy tube.

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# Tracheostomy tubes —

## Part 1: Connectors for tubes for adults

### 1 Scope

This part of ISO 5366 specifies requirements for connectors for tracheostomy tubes of designated inside diameter 6,5 mm or greater, for use on patients undergoing surgical operations and/or those for whom artificial ventilation or other respiratory support may be required.

### 2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 5366. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5366 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

### 3 Definitions

For the purposes of this part of ISO 5366, the following definitions apply.

**3.1 tracheostomy tube:** Tube designed for insertion into the trachea through a tracheostomy. [ISO 4135:—<sup>1)</sup>, definition 6.8]

### 3.2 machine end:

(1) End of the tracheostomy tube which is intended to project from the neck of the patient.

(2) End of connector intended to mate with the breathing system of an anaesthetic machine or ventilator.

[adapted from ISO 4135:—<sup>1)</sup>, definition 6.8.1]

## 4 Connectors

**4.1** Tracheostomy tubes shall have at the machine end a permanently attached male 15 mm conical connector in accordance with ISO 5356-1. The inside diameter of the conical element shall be not less than the designated inside diameter of the tube to which it is attached.

**4.2** Any transition in inside diameter shall be tapered to give an adequate lead-in for passage of a suction catheter.

1) To be published. (Revision of ISO 4135:1979, *Anaesthesiology — Vocabulary*.)

**Annex A**  
(informative)

**Guidance on design of retaining devices**

**A.1** It is recommended that the design should permit the fitting of a retaining or locking device to provide added security of attachment of the conical fittings.

Such a device may, however, introduce other hazards such as that of accidental extubation. It should, therefore, be as light and compact as possible.

**A.2** Any projections (for example hooks, lugs or studs) should be designed so as to minimize the risk of their catching on attendants' hands, surgical dressings or other equipment.

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**Descriptors:** medical equipment, anaesthetic equipment, artificial breathing apparatus, tracheostomy tubes, connectors, specifications.

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